

II. REMARKS

Formal Matters

Claims 1-24 are pending after entry of the amendments set forth herein.

Claims 1-5, 8, and 12-16 were examined and were rejected. Claims 6, 10, and 11 were withdrawn from consideration. Claims 7 and 9 were objected to

Claims 17-24 are added. Support for new claims 17-24 is found in the claims as originally filed, and throughout the specification, including the following exemplary locations: Examples 1 and 2. Accordingly, no new matter is added by these new claims.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Allowable subject matter

Applicants note with gratitude that claims 7 and 9 were considered allowable if rewritten in independent form.

Finality of Office Action

The instant Office Action was indicated as being final. However, the Patent Application Information Retrieval indicates that the instant Office Action is a non-final Office Action.

Finality of an Office Action in the instant case is not proper. As indicated in MPEP §706.07(a), a second or any subsequent action on the merit shall be made final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement (IDS) filed during the period set forth in 37 C.F.R. §1.97(c). The instant Office Action raises new grounds of rejection that were neither necessitated by applicant's amendment of the claims nor based on information submitted in an IDS. Accordingly, the finality of the instant Office Action is not proper. Applicants respectfully request that the finality be withdrawn.

Withdrawal of previous rejections

The following rejections, raised in the February 19, 2003 Office Action, have not been reiterated in the instant Office Action, and are thus presumed to have been withdrawn: (1) rejection of claims 1-5, 7-9, 12, and 16 under 35 U.S.C. §102(a) over WO 99/60017; and (2) rejection of claims 1-5, 7-9, and 12-

16 under 35 U.S.C. §103 over Reynolds (U.S. Patent No. 5,015,628) in view of WO 99/60017 and Kumagai (U.S. Patent No. 5,837,674).

Rejection under 35 U.S.C. §112, second paragraph

Claims 3 and 16 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

The Office Action stated that the language “in naturally occurring protein matrix extracellular phosphoglycoprotein” is vague as it is unclear how a naturally occurring protein would differ from a synthetically made protein. Applicants respectfully traverse the rejection.

The language “in naturally occurring protein matrix extracellular phosphoglycoprotein” does not render claims 3 and 16 indefinite. Contrary to the assertion in the Office Action, the term “in naturally occurring protein matrix extracellular phosphoglycoprotein” does not imply that the protein would differ from a synthetically made protein. The term is included merely to indicate that the RDG sequence is contiguous with a sequence found in naturally occurring matrix extracellular phosphoglycoprotein, in contrast to, e.g., a matrix extracellular phosphoglycoprotein that was manipulated in the laboratory to include one or more amino acid changes compared to a naturally-occurring matrix extracellular phosphoglycoprotein.

Applicants submit that the rejection of claims 3 and 16 under 35 U.S.C. §112, second paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C. §102(b)

Claims 1-5, 8, 12, 13, and 16 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Cheng et al. (U.S. Patent No. 5,849,865; “Cheng”).

The Office Action stated that Cheng teaches a composition comprising a peptide consisting of about 15 amino acid residues in length, citing SEQ ID NOs: 33 and 34 of Cheng. Applicants respectfully traverse the rejection.

Cheng discusses circular peptides. For example, SEQ ID NO:33 and SEQ ID NO:34 of Cheng are circular (cyclic) peptides. Cheng, columns 49-52. The instant invention relates to peptide compounds that are linear. Accordingly, Cheng cannot anticipate the instant invention as claimed.

Applicants further note that SEQ ID NOs:33 and 34 of Cheng are 11 amino acids in length, not 15 amino acids in length as asserted in the Office Action. Therefore this rejection is not properly applied to claim 4, which recites that the peptide has a length of from about 15 to about 35 amino acids.

Furthermore, Cheng states that the peptides discussed therein inhibit bone resorption, and that they do so by inhibiting binding of osteoclasts to bone matrix. Cheng, Abstract; and column 1, lines 56-64. In contrast, the peptides as claimed in the instant application enhance bone growth.

Applicants submit that the rejection of claims 1-5, 8, 12, 13, and 16 under 35 U.S.C. §102(b) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C. §103

Claims 1-5, 8, and 12-16 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Cheng in view of Cerny et al. (U.S. Patent No. 6,300,062; "Cerny"). Claims 1-5, 7-9, 12, 13, and 16 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Cheng as applied to claims 1-5, 8, 12, 13, and 16, and further in view of Rowe et al. ((2000) *Genomics* 67:54-68).

Claims 1-5, 8, and 12-16 over Cheng in view of Cerny

The Office Action stated that: (1) Cheng teaches a composition comprising a peptide consisting of about 15 amino acid residues in length, citing SEQ ID NOs: 33 and 34 of Cheng; (2) Cheng does not teach a composition that is a toothpaste or mouthwash; (3) Cerny teaches the administration of both mouthwash and toothpaste comprising an RGD peptide in promoting bone growth. The Office Action stated that it would have been obvious to use the RGD peptide taught by Cheng in a toothpaste or flavored mouthwash to promote bone growth and maintain healthy teeth. Applicants respectfully traverse the rejection.

Applicants submit that this rejection is not properly applied to claims 1-5, 8, 12, 13, and 16. Applicants note that only claims 14 and 15 specifically recite "a toothpaste" and "a mouthwash." Accordingly, Applicants will respond to this rejection as it might apply to claims 14 and 15.

As noted above, Cheng discusses circular peptides, not linear peptides. Cerny does not cure the deficiency of Cheng. Accordingly, Cheng, alone or in combination with Cerny, cannot render the instant claims obvious.

Claims 1-5, 7-9, 12, 13, and 16 over Cheng in view of Cerny and Rowe

The Office Action stated that Rowe teaches an RGD region consisting of about 22 amino acid residues. The Office Action stated that it would have been obvious to create an isolated peptide from the specific region taught by Rowe for use in promoting bone growth. Applicants respectfully traverse the rejection.

First, as noted above, Cheng discusses circular peptides, not linear peptides as disclosed in the instant application. Neither Cerny nor Rowe cures the deficiencies of Cheng.

The Office Action pointed to amino acids 242-264 of Figure 1; the Abstract; and page 60, column 2, last four lines of Rowe. However, the Abstract of Rowe merely states that a new gene, termed MEPE, was identified, and that the encoded protein contains an RGD sequence proposed to be essential for integrin-receptor interactions. There is no disclosure or suggestion in the Abstract of any peptide of 10-50 amino acids in length, as recited in claim 1. Page 60, column 2, last four lines of Rowe merely discusses the amino acid sequence of the MEPE protein, and states that the protein includes an RGD cell attachment motif at residues 247-249. Nowhere in Rowe is there any mention of a peptide corresponding to amino acids 242-264 as being useful to enhance bone growth. Nowhere in Rowe is there any suggestion to make a peptide corresponding to amino acids 242-264.

There is no disclosure or suggestion in Rowe of any peptide of 10-50 amino acids in length and comprising an integrin binding motif, e.g., an RGD motif, which peptide is effective in enhancing bone growth. Accordingly, Rowe cannot render the instant claims obvious.

Conclusion as to the rejections under 35 U.S.C. §103

Applicants submit that the rejection of the claims discussed above under 35 U.S.C. §103 has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

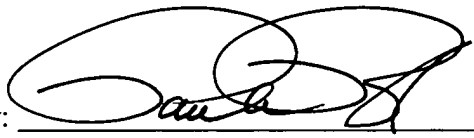
III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number BEAR006.

Respectfully submitted,
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